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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,235	11/06/2001	Seth Lederman	2516-1-002N	5392

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/992,235	LEDERMAN ET AL.
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 September 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

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DETAILED ACTION

1. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter et al., 5,462,746 or Midha et al., 6,217,904.
2. Claims 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al., supra in view of Wolter et al., supra.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to applicant's amendment received Sep. 3, 2002.

No claims are cancelled. No new claims are added.

Claims 1-22 are currently pending.

The previous objection of claim 17, set forth in paragraph 1 of the office action mailed March 26, 2002, is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous grounds of rejection under 35 USC 103(a), set forth in paragraphs 2-5 of the office action mailed March 26, 2002 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed March 26, 2002 with the following additional comment:

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It is Applicant's position that the prior art does not disclose or fairly suggest Applicant's claimed methods and compositions. Specifically, it is argued that Applicant ha discovered that the claimed stereoisomer possesses unexpected properties as evidenced by the Table on page 33, lines 7-15 of the specification. Moreover, it is Applicant's position that the beneficial effects (less stereotypic behavior; improved and unexpected pharmacologic and dose responsive effects) of the claimed stereoisomer are unexpected and one of ordinary skill in the art would not have been motivated to isolate the pure R amphetaminil to arrive at the claimed composition and method.

Said arguments have been considered but are not found to be persuasive.

The evidence in the form of data and statements set forth in the specification have been noted; however, the Examiner respectfully submits that such evidence appears to support the assertion that one isomer is expected to be more active than other isomers. In other words, the data showing greater activity appears to be expected absent further clarification or arguments of superior results. Applicant's arguments and the Table in the specification have been well noted; however, it is not clear on the record how the numbers in the Table reflect unexpected properties. It appears as if Applicant is arguing that which is already expected, i.e. that one isomer is expected to have greater activity than other isomers. It is for these reasons that the rejection is respectfully maintained.

New Ground of Rejection

Claim Rejections - 35 USC § 112

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4. Claims 9-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method of preventing a human condition or disease requiring or benefitting from a CNS stimulant, wherein the human condition or disease comprises the various disorders set forth in claim 21, i.e Alzheimer's disease, Parkinson's disease etc.

(2) The state of the prior art

While the art recognizes the treatment of Parkinson's or Alzheimer's disease, (please see art relied upon in the rejection), the art does not recognize, however, therapeutic remedies which result in the complete prevention of said diseases.

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(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are broad and encompass numerous conditions or diseases as well as the specific diseases set forth in claim 21.

(6) The amount of direction or guidance presented

Applicant's specification provides guidance for and is only enabled for the use of (R,R'), (R,S')-amphetaminil in the treatment of the claimed disorders. However, the specification provides no guidance, in the way of written description, to enable one of ordinary skill in the art to prevent diseases such as Alzheimer's disease or Parkinson's disease. Applicant's specification does not enable one of ordinary skill in the art to use compositions containing (R,R'), (R,S')-amphetaminil in the prevention of such disorders.

(7) The presence or absence of working examples

The examples in Applicant's specification describe using (R,R'), (R,S')-amphetaminil for studying locomotor activity and the induction of stereotyped behavior in normal rats. Please see Example 4.

(8) The quantity of experimentation necessary

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Since prevention of diseases such as Alzheimer's or Parkinson's disease has not been achieved and thus recognized in the art, and since Applicant's specification only provides locomotor or stereotypy data from studies in rats, one of ordinary skill in the art would be burdened with undue experimentation to determine the pharmacological parameters i.e. dosage, etc. necessary to enable one of ordinary skill in the art to actually prevent the occurrence of Parkinson's or Alzheimer's disease.

The Examiner respectfully suggests amending claim 9 by cancelling "prophylaxis" from the claim.

Conclusion

Claims 1-22 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM *CDM*

Dec. 1, 2002

Cybille DM
Cybille Delacroix-Muirheid
Patent Examiner Group 1600